

Ionizing Radiation Division		IRD-G-01
GUIDE AND PROCEDURE WRITING		

## Purpose

This protocol provides an outline of elements necessary to write Guides and Procedures within the Ionizing Radiation Division (IRD).

## Scope

This protocol applies to all Guides and Procedures written in support of the IRD calibration, measurement quality assurance, and standard reference material programs.

## Definitions

Guide – Basic information and instructions on the operational aspects of the IRD Quality System.

Procedure – A set of detailed instructions that describe the steps required to perform a calibration, measurement quality assurance, or standard reference material service.

## Protocol

### Part 1 - IRD Guides

1. The Guide templates are obtained from the Quality Manager.
2. The obligatory sections to be included are as follows: Approvals, Purpose, Scope, Protocol, Acceptance Criteria, Records, Filing and Retention. If any of these sections do not apply, a “N/A” must be entered. [NOTE: The Approvals section is a signature page that does not appear in the Internet (uncontrolled) version of the Guide.]
3. Optional sections to be filled in are: Definitions, Equipment, Health & Safety Precautions, References, and Appendices. If these do not apply, they may be omitted from the Guide.
4. Additional sections may be added to fit individual needs.
5. Specific guidelines for each section may be obtained from the Quality Manager.

### *Review of IRD Guides*

1. Once written, the Guide is distributed to IRD staff for review for consistency with common practices.

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2. The Guide is reviewed by each of the Group Leaders to ensure that it does not conflict with the operational aspects of IRD services.
3. The Quality Manager reviews the Guide to ensure that all items dealing with quality (documents, records, etc.) are handled in the correct manner.
4. The IRD Division Chief reviews the Guide to ensure that it adheres to Division policy.
5. The Guide is approved when all signatures are recorded in the Approvals list.

#### *Distribution*

Once all parties approve a Guide, it shall be given to the Quality Manager who will assign it a number and will add it to the master list of controlled documents. The master list of controlled documents will be updated to reflect any revisions. Copies will then be made and distributed by the Quality Manager as appropriate.

The Quality Manager is under no obligation to provide updated Guides to bearers of uncontrolled quality system documentation.

#### *Guide Revision*

1. At least biannually, the Quality Manager will initiate the review process.
2. Guides are to be revised when a change is warranted.
3. A reviewer shall obtain and complete a Guide Review Form, Appendix IRD-G-01.A. This form is then returned to the Quality Manager along with the original of the revised Guide.
4. The Quality Manager shall make the revised Guide available to IRD staff and is responsible for updating all controlled copies.
5. The Quality Manager has the option of issuing errata sheets rather than revised procedures in the interim between official revisions.

#### *Deleted Guides*

1. A Guide will be deleted when:
  - it is no longer in effect
  - there is a change of name and/or number

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2. The reviewers shall complete a Guide Review Form, Appendix IRD-G-01.A. This completed form shall be returned to the Quality Manager.
3. The Quality Manager shall remove the deleted Guide from the IRD files and place it in the Deleted Documents notebook.
4. The Quality Manager will issue a notice to remove the Guide from all controlled copies of the procedure manual.

## Part 2 – Technical Service Procedures

1. There is no set format for calibration service Procedures. They should be written in an easy-to-understand format appropriate to the particular service.
2. The obligatory section headings to be included are: Purpose, Scope, Definitions, Equipment, Safety, Procedures, Uncertainty Analysis, Records, References, Filing and Retention. Other sections may be added as deemed appropriate.
3. Authors are encouraged to consider the NIST-QM-I and IRD-QM-II as guidance in preparing the content of their (calibration or SRM) service Procedure. The following list of sections from NIST-QM-I and IRD-QM-II are of particular relevance: (4.3) Control of Documents, Records, and Data; (5.4) Calibration and Certification Procedures; (5.5) Equipment; (5.6) Measurement Traceability; (5.7) Sampling; (5.8) Handling of Test and Calibration Items; (5.9) Quality Assurance Practices; and, (5.10) Reporting Results.
4. The Procedure shall be consistent with the NIST Quality System.

## *Review of Procedures*

1. A reviewer shall obtain and complete a Guide Review Form, Appendix IRD-G-01.A. This form is then returned to the Quality Manager along with the original of the revised Guide.
2. Once written, an independent reviewer reviews the Procedure.
  - 2.1 This person should be familiar, but not necessarily intimately involved, with the calibration/testing program in the Procedure.
  - 2.2 If possible, the independent reviewer should visit the measurement facility to either perform the Procedure or simulate the steps involved.
3. The Group Leader shall review the Procedure to ensure that it meets Group policy and operational requirements.

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4. The Quality Manager shall review the Procedure to ensure that quality requirements are being met.
5. The IRD Division Chief reviews the Procedure to ensure that it adheres to Division policy.
6. The Procedure is approved when all Guide Review Forms are returned and the IRD Division Chief signature is recorded.

#### *Distribution*

Once all parties approve a calibration service manual, it shall be given to the Quality Manager who will assign it a number and will add it to the master list of controlled documents. The master list of controlled documents will be updated to reflect any revisions. Copies will then be made and distributed by the Quality Manager as appropriate.

The Quality Manager is under no obligation to provide updated Procedures to bearers of uncontrolled quality system documentation. These documents may be published with an understanding that the published version does not necessarily reflect the current state of the calibration service. Published versions of the calibration service manuals may be distributed freely or placed on the internet.

#### *Procedure Revision and Deleted Calibration Service Manuals*

Same as for IRD Guides above.

#### **Acceptance Criteria**

A Guide or Procedure will be considered accepted once the signatures on the approval page are completed. A new approval sheet must be signed to acknowledge acceptance of any revision to a Guide or Procedure.

#### **Schedule**

Once written, Guides and Procedures will be reviewed at least biannually.

#### **Records**

Master list of controlled documents  
IRD Guides  
IRD Procedures  
Guide and Procedure review schedule  
Deleted Documents notebook

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## **Filing and Retention**

The master list of controlled documents is filed at the beginning of the Master Quality System Documentation notebook and shall be retained only until the next list is prepared.

The Quality Manager shall maintain the original of all current versions of IRD Guides and Procedures in the Master Quality System Documentation notebook. Copies of the current revision of Guides and Procedures shall be placed in controlled Quality Manuals.

The Quality Manager shall maintain the Guide and Procedure review schedule, along with responses. These documents shall be retained until such time as the revision, if any, is made.

All deleted Guides and Procedures (including old revisions) shall be placed in the Deleted Documents notebook. The Quality Manager shall maintain this notebook. All old revisions shall be maintained until such time as it is decided to delete the Guide or Procedure altogether. Once the decision has been made to delete the Guide or Procedure, only the last revision shall be maintained in the Deleted Documents notebook.

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Appendix IRD-G-01.A

## GUIDE/PROCEDURE REVIEW

Guide/Procedure # \_\_\_\_\_ Guide/Procedure Name \_\_\_\_\_

Reviewed by \_\_\_\_\_ Date \_\_\_\_\_

Approved by \_\_\_\_\_ Date \_\_\_\_\_

\_\_\_\_\_ Guide/Procedure requires no revision.

\_\_\_\_\_ Guide/Procedure requires revision, revised Guide/Procedure attached.

\_\_\_\_\_ Guide/Procedure should be removed from IRD-QM-II manual, explanation below.

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